

# The effect of listening to music on pain experienced during a prostate biopsy. A randomized controlled trial.

Gepubliceerd: 11-02-2017 Laatste bijgewerkt: 18-08-2022

Listening to music by using an audio pillow, will reduce the pain experienced during an ultrasound-guided prostate biopsy,

<b>Ethische beoordeling</b>	Niet van toepassing
<b>Status</b>	Werving gestart
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON27997

### Bron

Nationaal Trial Register

### Verkorte titel

Not applicable

### Aandoening

Pain, prostate biopsy

Pijn, prostaatbiopsie

### Ondersteuning

**Primaire sponsor:** Sponsor Ziekenhuis Gelderse Vallei

postadres P.O. Box 9025

postcode 6710 HN

stad Ede

land The Netherlands

**Overige ondersteuning:** Ziekenhuis Gelderse Vallei

### Onderzoeksproduct en/of interventie

# Uitkomstmaten

## Primaire uitkomstmaten

Pain level before and maximum pain level during the prostate biopsy, as assessed with a Visual Analogue Scale (VAS) for pain.

## Toelichting onderzoek

### Achtergrond van het onderzoek

Background:

In hospitals examinations and treatments are performed in which the patient experiences acute pain. Pain can be reduced by using pharmacological or non-pharmacological interventions or a combination of both. Listening to music is a non-pharmacological, non-invasive, inexpensive, safe and effective method to reduce pain and anxiety in painful interventions. It is widely used in the treatment of acute pain and has demonstrated a reduction in pain experience in various medical procedures. Men who undergo prostate biopsy often experience pain and fear.

Objective:

To determine if patients who undergo an ultrasound-guided prostate biopsy experience less pain when listening to relaxing and stress-reducing music during the prostate biopsy.

Study design:

Randomized controlled trial.

Primary outcome:

Level of pain before and maximum level during the prostate biopsy as assessed with a Visual Analogue Scale for pain (a straight horizontal line of fixed length, usually 100 mm, with the left end representing 'no pain' and the right end representing 'the worst pain imaginable').

Secondary outcome:

Level of anxiety before and during the prostate biopsy as assessed with a Visual Analogue Scale for anxiety (a straight horizontal line of fixed length, usually 100 mm, with the left end representing no anxiety and the right end representing 'the most anxiety imaginable'). Acceptability of the pain. This question can be answered with "yes" or "no."

Study population:

60 men suspected of having prostate cancer and scheduled for transrectal ultrasound-guided prostate biopsy between December 2016 and May 2017 in Hospital Gelderse Vallei Ede.

Inclusiecriteria:

- Age  $\geq 35$  years
- Prostate biopsy to confirm or deny the presence of prostate cancer (in addition to elevated prostate-specific antigen and/or abnormal (digital) rectal examination findings)
- Signed informed consent

Exclusiecriteria:

- Prostate biopsy in combination with another physical examination, such as cystoscopy
- Request for an anaesthetic during the prostate biopsy
- Previously having had a prostate biopsy
- Hearing impairment or blindness
- Problems in the rectal area (haemorrhoids, anal fissure or clinically evident prostatitis)

## **Doel van het onderzoek**

Listening to music by using an audio pillow, will reduce the pain experienced during an ultrasound-guided prostate biopsy,

## **Onderzoeksopzet**

There will be two assessment times:

1. Before the prostate biopsy: VAS for pain and VAS for anxiety

2. Immediately after the prostate biopsy: VAS for pain and VAS for anxiety (to retrospectively assess the maximum level during the prostate biopsy), and acceptability of pain.

### **Onderzoeksproduct en/of interventie**

Patients are randomly allocated to one of the two groups:

1. Intervention group: usual care with music intervention during prostate biopsy
2. Control group: usual care during prostate biopsy

The music intervention consists of relaxing and stress-reducing music, using an audio pillow. The music is standardly put on a volume of 50 dB and can be adapted to a for the participant pleasant volume (up to 60 dB).

## **Contactpersonen**

### **Publiek**

Polikliniek Urologie

Machteld Molkenboer-Oortwijn  
Willy Brandtlaan 10

Ede 6716 RP  
The Netherlands  
+31 (0)318 433 086

### **Wetenschappelijk**

Polikliniek Urologie

Machteld Molkenboer-Oortwijn  
Willy Brandtlaan 10

Ede 6716 RP  
The Netherlands  
+31 (0)318 433 086

## **Deelname eisen**

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age  $\geq 35$  years
- Prostate biopsy to confirm or deny the presence of prostate cancer (in addition to elevated prostate-specific antigen and/or abnormal (digital) rectal examination findings)
- Signed informed consent

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Prostate biopsy in combination with another physical examination, such as cystoscopy
- Request for an anaesthetic during the prostate biopsy
- Previously having had a prostate biopsy
- Hearing impairment or blindness
- Problems in the rectal area (haemorrhoids, anal fissure or clinically evident prostatitis)

## Onderzoeksopzet

### Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

### Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-12-2016

Aantal proefpersonen: 60  
Type: Verwachte startdatum

## Ethische beoordeling

Niet van toepassing  
Soort: Niet van toepassing

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

Register	ID
----------	----

NTR-new	NL6088
---------	--------

NTR-old	NTR6235
---------	---------

Ander register identifying number 1611-597 : Ziekenhuis Gelderse Vallei

## Resultaten